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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,896	08/01/2003	Klaus Preissner	06478.1491	9809

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EXAMINER	
BOWMAN, AMY HUDSON	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 09/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/631,896	**Applicant(s)** PREISSNER ET AL.	
	Examiner Amy H. Bowman	**Art Unit** 1635	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 August 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,3 and 13*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

JAMES SCHULTZ, PH.D.
PRIMARY EXAMINER

Continuation of 11. does NOT place the application in condition for allowance because:

Applicant has amended claim 1 to eliminate "pharmaceutical preparation", thereby obviating the enablement rejection with regards to treatment. However, as explained in the office action mailed on 4/28/2006, applicant has not demonstrated how a peptide-nucleic acid would promote coagulation, as instantly recited.

In response, applicant argues that one skilled in the art would recognize that if one were to add more than one type of PNA or RNA together to the outside of the cell, they would not add molecules with complementary sequences. Applicant argues that the likelihood of having some native RNA that performs some coagulation function that happens to have a complementary sequence to the PNA applied is extremely remote.

It appears that applicant is relying on PNAs to promote coagulation simply based on the fact that they are RNA compounds. Applicant asserts that the accepted use of PNAs to act as inhibitory molecules does not apply in the instant case because PNAs are known inhibitory molecules inside of the cell, whereas the instant invention is designed to function exterior to the cell.

However, upon a review of the art, PNAs are known to function as inhibitory molecules, rather than as enhancers of coagulation. In absence of an understanding of such a function in the art, the examiner must look to the instant specification to teach how one of ordinary skill in the art could practice the invention without undue experimentation. In the instant case, the specification does not teach how a PNA, that is commonly known for inhibitory abilities, would enhance coagulation. Therefore, one of ordinary skill in the art would not know how to make and use the invention without undue experimentation.

Additionally, the arguments provided by applicant regarding the rejection under 35 U.S.C. 102(b) are not considered persuasive. Applicant asserts that Shimkets et al. do not disclose that a nucleic acid or peptide-nucleic acid can enhance coagulation. The examiner is relying upon Shimkets et al. for teaching that PNAs were known inhibitory molecules, whereas Braasch et al. was relied upon for teaching that an elevated oligonucleotide dose can lead to nonselective toxicity and cell death. Therefore, any PNA of the prior art, such as the PNAs taught by Shimkets et al. or Moore et al., formulated in a pharmaceutical composition would qualify as prior art when present in a high enough concentration to induce toxicity, since toxicity is correlated to a promotion of coagulation, as instantly recited.

In absence of a teaching to draw a nexus between PNAs and increased coagulation, increased dosage of PNAs to a level of toxicity is the only possible mechanism found by the examiner to explain how a PNA would enhance coagulation, as instantly recited.

Applicant further argues that the claims further require an activator for a plasma coagulation factor. Applicant asserts that the specification defines various activators for plasma coagulation factor. Contrary to applicant's assertion, the specification does not define "activator for plasma coagulation factor", but rather discloses "particularly suitable activators". Since the specification does not define "activator for plasma coagulation factor", any RNA is embraced by this terminology because the specification discloses that any RNA can be a procoagulant cofactor, thereby activating plasma coagulation factor by serving as a cofactor to FSAP. Therefore, the compositions taught by Shimkets et al. and Moore et al. that comprise RNA and a PNA anticipate the instant invention.